<u>REMARKS</u>

Claims 1-19 are pending and stand rejected. Minor amendments have been made to claims 1 and 7, and new claims 21 to 25 have been added. The material in the new claims is supported at least in the portions of the application highlighted below. Applicants respectfully request reconsideration and allowance based on the following remarks.

The Invention

Applicants' invention is directed to a suture anchor that is particularly useful in small bones. In fact, the title of the application is "Bioabsorbable Suture Anchor System for Use in Small Joints." The "Summary of the Invention" states:

The present invention provides a system for anchoring soft tissue to bone using a bioabsorbable suture anchor for anchoring soft tissue to a bone of a small joint. The suture anchor is configured to toggle and anchor itself inside a bone cavity of a small joint. $[\P 8.^1]$

That is, the anchor of the application is sized and configured particularly to be toggled inside small bones such as those found in the smaller joints in the body in order to repair soft tissue in those areas. These applications are described in more detail in the "Detailed Description of the Invention" as follows:

The suture anchors 10, 110 of the present invention are configured and sized such that they can be used, with sutures, in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand. Additionally, these anchors 10, 110 can be used to attach soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. Therefore, the suture anchors 10, 110 should have a length sufficient to enable them to properly seat within a small bone such as those mentioned, but be sized and configured to be effective in a surgery to reattach soft tissue to such bone. To this end, the suture anchors

¹ Citations to the application refer to the paragraph numbering of the application as published as US 2005/0019368 A1.

10, 110 of the present invention have a length in the range of about 2 to about 6 mm. Additionally, the width of the second, trailing end 16, 116 is in the range of about 1 to about 3 mm at its widest portion. It is contemplated that suture anchors 10, 110 dimensioned within these ranges are suitable for use in a bone cavity that is no more than about 5 to 10 mm in depth. [¶28.]

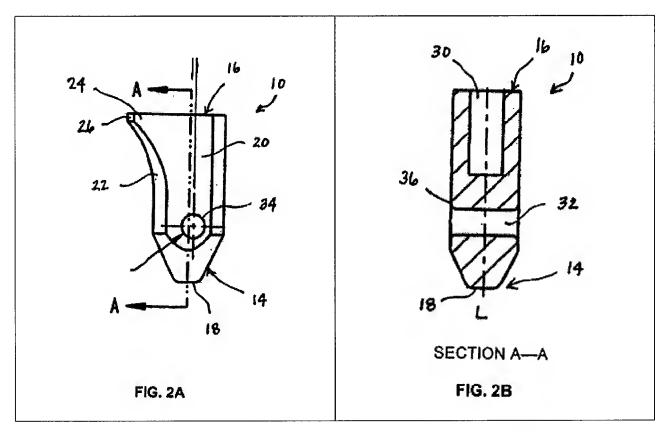
A preferred structure for performing these function is further described in the Summary of the Invention:

The suture anchor also includes a suture channel that extends between the two opposed surfaces. The suture channel is formed in the elongate body to allow the passage of a suture strand therethrough, and it is preferably oriented to be transverse to the longitudinal axis of the anchor. The suture channel is flanked, or bordered on each side by an opening that is located on an opposed surface. To enable the suture strand to glide smoothly around the suture channel, the openings can be provided with rims that are flared or chamfered so as to avoid snagging or cutting the suture strand on a sharp edge of the opening as the suture strand passes back and forth within the suture channel. The center of each of the openings can be longitudinally offset with respect to the longitudinal axis of the elongate body. The offset channel enables a surgeon to toggle the suture anchor by pulling on an attached suture strand while the anchor is inside a bone cavity. [9.]

Again, the structure and configuration of an anchor meeting these functions is further described in the application in the Detailed Description of the Invention:

The elongate body 12 also includes a suture channel 32 for passage of a suture strand through the suture anchor 10. As shown in FIG. 2B, the suture channel 32 extends in a direction transverse to the longitudinal axis L of the elongate body 12 and through each of the opposed surfaces 20 of suture anchor 10. The suture channel 32 is flanked, or bordered on each side by an opening 34 that is located on an opposed surface 20. To enable an attached suture strand to glide smoothly around the suture channel 32, the openings can be provided with a rim 36 that has a smooth, or flared, edge so as to avoid snagging or cutting the suture strand on a sharp edge of the opening 34 as the suture strand is passed back and forth within the suture channel 32. As illustrated in FIG. 2A, a center of the

opening 34 is longitudinally offset with respect to the longitudinal axis L of the body 12. Preferably, the center of the opening 34 is located away from the longitudinal axis L on the side of the axis opposite the flared portion 24. The offset suture channel 32 enables a surgeon to toggle the suture anchor 10 by pulling on an attached suture strand when the suture anchor 10 is inside a bone cavity. [\P 26.]



The claims presented incorporate various of these described features – features that are distinct from those in the prior art.

Rejections Pursuant to 35 U.S.C. § 102(e)

The Examiner rejects claims 1, 3-13, 15-16, 18, and 19-20 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,773,436 (Donnelly et al.).

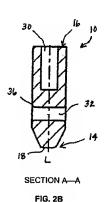
Substantially Transverse

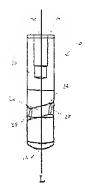
While the Examiner insists that each of the recitations found in the aforementioned

claims of Applicants' suture anchor are disclosed by Donnelly, the Examiner particularly focuses on the following recitation of independent claims 1, 15, and 19: "the suture channel...being oriented substantially transverse to the longitudinal axis of symmetry of the body." Applicants aver that Donnelly does not disclose, teach or suggest this recitation. In particular, the Examiner states:

Applicant's arguments filed on November 22, 2006 with respect to [the] Donnelley reference that does not [disclose] a suture channel formed in an elongated body wherein the suture channel is oriented substantially transverse to a longitudinal axis of symmetry of the body have been fully considered but [are] not persuasive. Examiner respectfully traverses the applicant's remarks: Since the definition of the word "traverse" according to the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 1256, is acting, lying, or being across : set crosswise. Therefore, the suture channel 24 as shown in Figures 1A and 1B is being cross with [sic] the longitudinal axis of symmetry (axis L shown in Figure 1A) meet the "transverse" limitation as claimed by applicant.

In significant part, independent claims 1, 15, and 19 recite a bone anchor having a suture channel formed in an elongate body for passage of a suture strand therethrough. The suture channel is oriented substantially transverse to a longitudinal axis of symmetry of the body. For example, as shown in FIG. 2B, which is reproduced to the right, the suture channel 32 extends between the two opposed surfaces and is oriented *transverse* to a longitudinal axis of symmetry (L) of the body. In use, the device is toggled by applying tension to a suture within the channel to effect engagement with bone.





P.4 28

Donnelly does not disclose, teach or suggest a suture anchor as required by claims 1, 15, and 19. Instead, the bone anchor of Donnelly requires that the suture channel be *obliquely angled* with respect to the longitudinal axis of the body of the anchor. In particular, as shown in FIG. 1B of Donnelly, which is reproduced to the left, with reference label L added, the suture channel 24 is *obliquely angled*

with respect to the longitudinal axis L of the body. This is completely opposite to the recitations of claims 1, 15, and 19, which require that the suture channel be oriented in a *substantially transverse* direction to the longitudinal axis of the body of the anchor. In fact, Donnelly never refers to its suture channel as being *substantially transverse* with respect to the longitudinal axis of the body of the anchor. The word *transverse* does not appear even once in Donnelly. This makes sense because Donnelly, rather than being focused on procedures in small bones that require precise proportions and movements of the anchor, relates to anchors that have a more complex toggling that maximizes the area of the anchor surface that engages bone.

The Examiner cites the Merriam-Webster's Collegiate Dictionary, Tenth Edition principal copyright 1993, page 1256 to define "transverse" to mean "acting, lying, or being across: set crosswise." This definition is incompatible with the language of the claim in which the suture channel is (1) "formed in the elongate body for passage of a suture strand therethrough;" and (2) "extending between the two opposed surfaces." A definition that includes "acting, lying or being" is inconsistent with this claim language that requires a much more specific configuration of the channel.

More importantly, the very same dictionary applied by the Examiner also defines "transverse" to mean "made at right angles to the long axis of the body." (Emphasis added.) This definition is clearly applicable to Applicants' use of transverse taken in light of the specification and the claims because Applicants claim the suture channel to be "substantially transverse with respect to the longitudinal axis of the body" – the claim uses verbatim the language from this definition.

Further, turning to a technical dictionary that is more relevant given its focus in the medical area, Dorland's Illustrated Medical Dictionary, 30th Edition principal copyright 2003, page 1938 defines "transverse" to mean "placed crosswise; situated at right angles to the long axis of a part." (Emphasis added.) Again Applicants point out the specific reference to transverse being at right angles with respect to the long axis of a part. In light of the

² The order of definitions is not indicative of importance or primacy, but merely reflects historical usage. Merriam-Webster's Collegiate Dictionary (11th ed. 2003) 19a ("Order of Senses")

specification, which continually makes reference to the suture channel extending in a direction transverse to *the longitudinal axis L of the elongate body 12*, it is clear that the appropriate definition of transverse is "at right angles to the longitudinal axis of the body." Donnelly does not disclose, teach or suggest such an orientation of a suture channel with respect to a longitudinal axis of the body.

In addition, Applicants add dependent claim 23 which expressly recites the dictionary definition of transverse.

Accordingly, because Donnelly does not teach each and every recitation of Applicants' claims, claims 1, 15, and 19, as well as claims 3-13, 16, 18 and new claims 21 to 25, which depend therefrom, distinguish over Donnelly and represent allowable subject matter. Further, dependent claim 23 expressly recites right angles, making claims 23 to 25 further patentable over Donnelly.

Center of the Opening

With regard to claim 7, the Examiner asserts that Donnelly discloses "the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 4a and 4b)." In response to the previous response, the Examiner states:

Applicant's arguments filed on November 22, 2006 with respect to [the] Donnelley [sic] reference that does [sic] the center of the opening is laterally offset with respect to the longitudinal axis of symmetry of the elongate body have been fully considered but [are] not persuasive. Examiner respectfully traverses the applicant's remarks: here it is noted that examiner [interprets] the limitation "a center" means a point. What [is] abundantly [clear] from figure 1A is that the center of the opening as shown on the front face 18 or the center of the opening as shown on the back face 18 is positioned offset or laterally offset with respect to the longitudinal axis of symmetry of the elongate body 12. Perhaps applicant intended to claim that the centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the elongate body.

Applicants not that claim 7 includes the following structural recitations: (1) elongate body having a longitudinal axis of symmetry; (2) two opposed surfaces; (3) a suture channel extending between the two opposed surfaces and being oriented substantially transverse to the longitudinal axis of symmetry; (4) openings on each of the two opposed surfaces at either end of the channel; and (5) a center of each opening being laterally offset from the longitudinal axis. Figure 2A (provided above) illustrates an embodiment having these features. First, definitionally with respect to claim 7, a channel with openings having these features will, geometrically, have a centerline that is offset from the longitudinal axis – there should be no need to separately recite it. Second. Applicants' arguments with respect to Donnelly, were not that the openings in Figure 1A are not offset – it was that the suture channel in Figure 1A is not transverse to the longitudinal axis because it is obliquely angled. Other embodiments in Donnelly have transverse suture channels - but those have openings that are not laterally offset. Accordingly, no suture channel in Donnelly is both transverse and laterally offset. Finally, Applicants have added dependent claims 21 and 24 which recite the language exactly as suggested by the Examiner. Accordingly, claims 7, 21 and 24, as well as the claims that depend therefrom, are patentably distinct from Donnelly for the further additional reason that Donnelly discloses no suture channel that is transverse and longitudinally offset from the longitudinal axis of symmetry of the body.

Rejections Pursuant to 35 U.S.C. § 103

U.S. Patent No. 6,773,436 (Donnelly)

The Examiner rejects claims 2, 3, 14, 15, 17, and 18 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,773,436 (Donnelly et al.). Claims 2, 3, and 14 depend from independent claim 1 and claims 17 and 18 depend from independent claim 15. As discussed above, independent claims 1 and 15 both distinguish over Donnelly. No further references are cited by the Examiner in this § 103(a) rejection. Accordingly, independent claim 15, as well as claims 2, 3, 14, 17, and 18 which depend from either independent claim 1 or 15, is allowable over Donnelly.

U.S. Patent No. 6,773,436 (Donnelly) in view of U.S. Patent No. 6,280,474 (Cassidy)

The Examiner rejects claims 2, 3, 17, and 18 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,773,436 (Donnelly et al.) in view of U.S. Patent No. 6,280,474 (Cassidy). Claims 2 and 3 depend from independent claim 1 and claims 17 and 18 depend from independent claim 15. As discussed above, independent claims 1 and 15 both distinguish over Donnelly. Cassidy fails to remedy the deficiencies. Accordingly, claims 2, 3, 17, and 18 are allowable over Donnelly in view of Cassidy at least because of their dependence from either independent claims 1 or 15.

CONCLUSION

Applicants submit that the pending claims are in condition for allowance, and allowance thereof is requested. The Applicant has filed an Interview Request Form herewith.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22956-214.

Dated: June 29, 2007 Respectfully submitted,

Ronald E. Cahill

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